REMARKS

Claims 1-9 and 27-59 are pending.

Applicants wish to further address the prior final rejection of Applicants' claims over Yu et al., US Patent 5,998,171. The Yu et al. patent refers to a polypeptide (and its' encoding DNA) called "endokine alpha". The patent discloses that the endokine alpha polypeptide is a purported member of the TNF family of cytokines, and specifically states that when its' sequence is aligned with that of human TNF-alpha, the endokine alpha polypeptide is about 30% similar and about 22% identical to human TNF-alpha. (Yu et al. Patent at Col. 6, lines 63-65; see also, Col. 5, lines 35-40; Figure 2).

Although the Yu et al. patent provides such structural information concerning endokine alpha, it fails to teach one of ordinary skill how to use such an endokine alpha polypeptide (or a DNA encoding it). The patent provides no functional data to suggest how the endokine alpha polypeptide or its' DNA may be used. Instead, the Yu et al. patent disclosure merely contains generic statements that the endokine alpha polypeptide can be tested in cytotoxity or proliferation assays (see, e.g., Col. 11, lines 55-64) or that its' nucleic acid may be utilized as a hybridization probe or PCR primer (see, e.g., Col. 11, lines 35-40). The only experimental data in the patent are the results of a Northern blot assay which revealed that the gene encoding endokine alpha was detected in human brain striatum and pancreas tissue. (Yu et al. Patent, Col. 36, lines 14-16).

Yu et al. attempt to "impute" the activity or use of endokine alpha by means of homology of the molecule to another known protein, TNF-alpha. Applicants submit that such an attempt to impute activity or use must fail for a number of reasons. First, the TNF family includes a relatively large number of molecules, and the homology of the endokine alpha polypeptide to TNF-alpha is relatively low. As mentioned above, Yu et al. report that endokine alpha polypeptide is only about 30% similar and only about 22% identical to human TNF-alpha. Furthermore, TNF-alpha is a polypeptide which has been characterized in the art as having a variety of different activities and properties. Indeed, in Col. 1, lines 27-54, Yu et al. admit that TNF is a "regulatory cytokine with

pleiotropic activities" and then provide a "laundry list" of such activities.

Applicants respectfully assert that until the endokine alpha had been analyzed for a function, it could simply not be predicted by the skilled artisan what the molecule could be used for or how it could be used. In this regard, the results obtained in the Northern blot analysis by Yu et al. clearly do not provide sufficient guidance to those skilled in the art what, if any, function the endokine alpha may possess, or if any such function would correlate with any of those in the laundry list of activities attributed to TNF-alpha. Those skilled in the art would clearly not be able to understand or predict from the disclosure in the Yu et al. patent what the use(s) of endokine alpha is, much less how to use endokine alpha. Accordingly, the Yu et al. patent falls significantly short of meeting the enablement requirements of Section 112.

It is also respectfully submitted that the Yu et al. patent disclosure fail to meet the written description requirement under Section 112. Because of the deficiencies in the teachings of the Yu et al. patent, as discussed above, it is clear that Yu et al. have not demonstrated possession of the endokine alpha (i.e., neither the DNA, protein, or antibodies thereto) nor methods of its use. Applicants submit that the Yu et al. patent cannot and should not be entitled to prior art status under Section 102(e) since it has not placed such disclosed and/or claimed compositions and methods in the possession of the public.

Respectfully submitted,

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Date: February 25, 2002

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